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### ***REMARKS***

This is a full and timely response to the outstanding non-final Office Action mailed February 23, 2006. Through this response, claim 10 has been amended. Reconsideration and allowance of the application and pending claims are respectfully requested.

#### **Continued Examination Under 37 C.F.R. 1.114**

Applicant thanks the Examiner for withdrawing the finality of the previous Office Action and for entering Applicant's submission filed on January 13, 2006.

#### **Withdrawal of Rejections**

Applicants thank the Examiner for careful consideration of Applicant's amendments and arguments filed previously, and the withdrawal of the rejection of the claims under 35 U.S.C. §112, 1<sup>st</sup> paragraph as allegedly not complying with the written description requirement.

#### **Response To Claim Rejections Under 35 U.S.C. §112, First Paragraph**

##### **A. Statement of the Rejection**

Claims 10-14 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner states that "[t]he claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *Office Action* at 2. Applicant respectfully traverses this rejection.

##### **B. Discussion of the Rejection**

First, claim 10 recites the following: "different sequences of the first plurality of nucleic acids can be differentiated by location" and "wherein the nucleotide sequence of each nucleic acid of the second plurality is known." (emphasis added). The claim is clearly enabled by the specification for the recited language. *See, e.g.*, specification at pp. 21-23 regarding the discussion of the universally spatially addressable array. Because the specification teaches how different sequences of the first plurality can be differentiated by location, and because the sequence of each acid of the second plurality is known, when the nucleic acids of the second plurality have hybridized to a target with a signal, and also to a first plurality, the sequence of the

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target can be determined. Applicant submits that on its face, claim 10 is clearly enabled by the specification.

In addition, Applicant has amended claim 10 to recite "a method of assaying target nucleic acid molecules by tagging and sorting the target molecules with a universal array..." (emphasis added). In view of this amendment, it is respectfully asserted that claims 10-14 define the invention in the manner required by 35 U.S.C. § 112. One skilled in the art, at the time the patent application was filed, would understand the term "universal array" and the fundamental concepts of how a universal array functions. In the specification itself, Applicant states the following: "[a]n alternative array-based method of analyzing nucleic acids has been described by several groups (Brenner USP 5,604,097; Morris et al. EP 97302313), and uses a universal spatially addressable array." *Specification* at p. 21, lines 18-20 (emphasis added). Furthermore, a brief perusal of issued patents prior to the filing of the instant application reveals that universal arrays were known and described in the art already. This is a completely appropriate method to determine if the specification is enabling for claims in a patent application.

The Manual of Patent Examination Procedure (MPEP) states the following:

The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application").... *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.).

*MPEP* §2164.05(a). In the instant case, there are at least two patent references that discuss and describe what universal arrays are, and how they function with the use of a first plurality and a second plurality of nucleic acids in addition to the target molecules.

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For example, U.S. Patent No. 6,268,147 issued to Beattie *et al.* on July 31, 2001 discusses and illustrates universal arrays at *e.g.*, FIGS. 1, 14A, 14B, 15A, 15B, and col. 35, line 60 – col. 35, line 67. By way of additional example, U.S. Patent No. 6,083,763 issued to Balch on July 4, 2000 also discusses universal arrays throughout, *e.g.*, at FIG. 5a and correlating discussion. Therefore, one of ordinary skill in the art upon reading the specification as of the date of the filing of the patent application would have understood how one is to determine the nucleotide sequence of a target molecule using a universal array.

Accordingly, Applicant respectfully requests that the rejections to these claims be withdrawn.

#### Response To Claim Rejections Under 35 U.S.C. §112, Second Paragraph

##### **A. Statement of the Rejection**

Claims 10-14 have been rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Office Action states:

Claim 10 is confusing where at line 3 of step “b)” reference is made to “each first region of each nucleic acid at a particular location.” Upon review of the claim, it appears that the members of the first plurality of nucleic acids have not been defined in terms of their having first and second regions, but rather, members of the second plurality have been so defined. Yet, it is the members of the first plurality that have been defined as being fixed at specific locations on a support. Accordingly, it appears that properties of the first and second plurality of nucleic acids are being incorrectly assigned/referenced.

*Office Action* at 7. Applicant has amended claim 10 to delete the references to first regions of the second plurality being at particular locations. Applicant respectfully requests that the rejection of claim 10 be withdrawn. Because claims 11-14 were rejected simply because they depend from claim 10 and fail to overcome the issues with claim 10, Applicant respectfully requests that the rejection of claims 11-14 also be withdrawn for the same reasons.

Applicant wishes to clarify that the foregoing amendments are cosmetic in nature and are not made as a condition for obtaining a patent. Applicant further submits that these amendments

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are non-narrowing and, pursuant to *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002), no prosecution history estoppel arises from the amendments. See also *Black & Decker, Inc. v. Hoover Svc. Ctr.*, 886 F.2d 1285, 1294 n. 13 (Fed. Cir. 1989); *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819 (Fed. Cir. 1988); *Hi-Life Prods. Inc. v. Am. Nat'l Water-Mattress Corp.*, 842 F.2d 323, 325 (Fed. Cir. 1988); *Mannesmann Demag Corp. v. Eng'd. Metal Prods. Co., Inc.*, 793 F.2d 1279, 1284-1285 (Fed. Cir. 1986); *Moeller v. Ionetics, Inc.*, 794 F.2d 653 (Fed. Cir. 1986).

Further, the Office Action states:

Claim 10 is confusing as to how the second region of a member of the second plurality of nucleic acids is defined in terms of its being able to hybridize to both the target nucleic acid and to a member of the first plurality of nucleic acids. Seemingly, it is the first region of a member of the second plurality that hybridizes to a member of the first plurality. And if it is possible for the second member to hybridize to both the target and a member of the first plurality, it is less than clear how one would be able to determine the nucleotide sequence of the target.

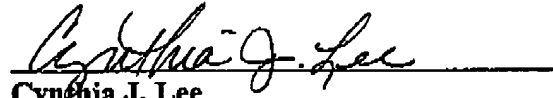
*Office Action* at 7. Applicant respectfully traverses the rejection. On the contrary, claim 10 recites "each second region of each nucleic acid of the second plurality comprises unstructured nucleotides such that the second region has a reduced ability to hybridize to a nucleic acid of the first plurality...." (emphasis added). Reconsideration of claims 10-14 in light of the recited portion of claim 10 is respectfully requested.

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**CONCLUSION**

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 10-14 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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